UNIVERSITY OF SOUTH ALABAMA

CT-101 GOOD CLINICAL PRACTICE

EFFECTIVE DATE: March 2023

Purpose

The Principal Investigator is the individual of record who assumes the authority and responsibility for the conduct of a clinical study. The purpose of this Policy and Procedure is to provide information on the responsibility of the investigator(s) in regards to Good Clinical Practice (GCP) and clinical trials. The rights and welfare of the individual clinical research subject must always be the paramount consideration in conducting clinical research. Accordingly, clinical research must be conducted in a manner that protects the rights, welfare and confidentiality of the human subject and also assures data credibility by protecting the integrity of accurate data that has been demonstrably collected according to the approved protocol.

Scope

This Policy and Procedure applies to Principal Investigators, Sub-Investigators, Clinical Research Coordinators, and any other USA personnel that perform significant, trial related tasks. USA non-research personnel who perform trial related tasks are not required to complete GCP training if the research task in which they will be performing is within their normal scope of practice and/or duties. This Policy and Procedure will also apply to non-USA personnel who perform significant trial related tasks on USA property or facilities.

Definitions

Good Clinical Practice: Good Clinical Practice (GCP) is an international ethical and scientific quality standard that helps ensure that the results of a clinical trial are credible and that the rights, welfare and confidentiality of the human subject are protected. Good Clinical Practice provides guidance on the best practices for the way a clinical trial is designed, conducted, performed, monitored, audited, recorded, analyzed, and reported.

Principal Investigator: The individual of record who assumes the authority and responsibility for the conduct of a clinical study.

Policy

Faculty and staff involved in the conduct, oversight, or management of clinical trials must complete training in GCP prior to conducting any research related activities. GCP training may be achieved

through a class or course, academic training program, or certification from a recognized clinical research professional organization. USA personnel have access to free GCP training through the CITI program. Information can be found on the Office of Research Compliance and Assurance's web page.

Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants.

Procedures

Completion of GCP training must be demonstrated prior to any applicable personnel conducting research related activities. GCP training should be refreshed at least every three years in order to remain current with regulations, standards and guidelines. GCP certificates should be kept in study-specific regulatory files. For studies performed through the Clinical Trials Office, a copy of all GCP certificates should be sent to the regulatory coordinator to be maintained with study records. Upon study closure, all GCP certificates should be archived with the study records in long-term storage.

Additional Resources

RESOURCES:
CITI PROGRAM

FEDERAL REFERENCES:
International Council for Harmonisation (ICH) Good Clinical Practice (E6)

History

N/A

Next Review Date

January 2026

Responsible Party

Director, Clinical Trials Office